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Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages

Supporting Statement for Paperwork Reduction Act Submission

Part A: Justification

**Task Order
#AG-3198-D-07-0102**

September 29, 2008

Prepared for
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USDA

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Part A. Justification

A.1 Explanation of Circumstances That Make the Collection of Data Necessary

The U.S. Department of Agriculture's (USDA) Food and Nutrition Service (FNS) is requesting approval from the Office of Management and Budget (OMB) to conduct interviews with WIC recipients and agency staff for the *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages Study*. The study is designed to evaluate the impacts that the regulatory changes to WIC food packages have on the incidence, duration, and intensity of breastfeeding. The overarching objective is to assess the effects of the Interim Rule published in the Federal Register, December 6, 2007, Volume 72, Number 234, pages 68968 -69302 that will be implemented by local WIC agencies (LWAs).

Background

The Special Supplemental Nutrition Program for Women, Infants and Children (WIC) has been providing nutritious foods to low-income women and children for over 30 years, as well as nutrition education, breastfeeding support, and health referral services. Among significant program benefits are food packages that are designed to supplement the diets of low-income individuals the program targets. Until recently, these food packages had remained virtually unchanged since the program's inception despite changes in nutritional science and health recommendations. On December 6, 2007, this Interim Rule changed the composition and quantities of prescribed foods in WIC food packages.

WIC foods are intended to "supplement" participants' food intakes and to be consumed along with other wholesome foods needed for a balanced diet. Under the prior WIC regulations, postpartum WIC mothers could choose among three WIC food packages:

- Package V (Pregnant and Breastfeeding Women), for mothers who partially breastfed their infants,
- Package VI (Non-breastfeeding and Postpartum Women), for mothers who fully formula fed their infant, or
- Package VII (Breastfeeding Women Enhanced Package), for fully breastfeeding mothers.

Women who chose Package V or VI also received Package I for their infant's first four months postpartum and Package II for months 4 through 12. Package I contained formula only, while Package II also included infant cereal and juice. No formula was provided to infants of women who chose Package VII.

The provisions of the Interim Rule revising the WIC food packages are based largely on recommendations from the Institute of Medicine (IOM). The IOM, at the request of the Food and Nutrition Service (FNS), conducted a comprehensive review of the WIC Food Packages (IOM, 2005). To promote and support the establishment of long-term breastfeeding success among postpartum WIC mothers, the IOM review committee (IOM, 2005) recommended:

...offering only two feeding options initially—full breastfeeding or full formula feeding. That is, formula would not be provided routinely during the first month after birth for any infants whose mothers intend to breastfeed. In a few circumstances, a small amount of powdered formula may be provided during the first month after birth if needed as the mother/infant pair establishes a pattern of breastfeeding.

In the spirit of the IOM recommendations, the new WIC food package rules establish maximum amounts of infant formula for infants who are partially breastfed, in addition to changing the content of mothers' packages. More specifically, the Interim Rule allowed partially breastfed infants in the first month to have only a small amount of formula (104 ounces per month). This small amount will provide a safeguard to women who want to breastfeed but may be less confident with a small amount to use. The formula could also be used for medically necessary situations, such as for infants with metabolic issues. In subsequent months, the maximum infant formula for partially breastfed infants is approximately one-half of the totals allotted for fully formula fed infants. The changes will be implemented by WIC State agencies between February 2008 and October 2009. Within this window, State agencies will determine their specific implementation timeframe for the new food packages based on the State assessment of changes required to its management information system, the training needs of staff, vendors and participants, and development of a new State food list.

The regulations for the formula packages, by increasing the attractiveness of the mother's package for fully breastfeeding women and greatly reducing the attractiveness of the partial breastfeeding option in the first month postpartum and reducing by half the maximum amount of the full-formula allotment in subsequent months, are designed to increase the initiation, intensity, and duration of breastfeeding. The underlying theory is that, by greatly reducing the attractiveness of the partial formula option for infants in the first month postpartum, more mothers will initiate breastfeeding and mothers who have difficulty breastfeeding during the first month may try harder to continue breastfeeding than if formula were readily available. In addition, if more limited amounts of formula are available to partially breastfeeding mothers in months 0 through 5 postpartum,¹ there is a greater likelihood that mothers will feed their infants relatively more breast milk than formula and do so for longer than if formula were more plentiful.

FNS intends that the limitation of formula for partially breastfed infants will encourage more women to establish breastfeeding successfully. However, the agency also recognizes that the rule change may have the unintended consequence of forcing a mother who is undecided about breastfeeding to choose the full-formula option because it is economically more attractive or as a safeguard in case she has difficulty with breastfeeding. There has also been some discussion that, although the partial breastfeeding packages are important options, they may keep some mothers from fully formula feeding. To document both intended and unintended consequences, and in response to recommendations from the IOM to study the effects of the rule change, FNS has funded this study to examine the effects of the changes in packages for postpartum women and infants on the initiation, intensity, and duration of breastfeeding.

Concerns about incidence, duration, and intensity of breastfeeding among WIC participants are warranted. In the *WIC Breastfeeding Design Study*, a design initiative conducted for FNS by Abt Associates, McLaughlin and her colleagues (McLaughlin et al., 2003) note that the WIC program faces challenges in breastfeeding promotion and support. WIC serves low-income populations that are traditionally less likely to breastfeed. Recent data (Abbott Laboratories, 2003) show that 59

¹ For clarification, the WIC terminology "0 to 5 months postpartum" corresponds to the first six months after birth.

percent of WIC women initiate breastfeeding, and 22 percent are still breastfeeding their infants at 5 months postpartum. Despite the gains that have been achieved in WIC, participants continue to lag behind non-WIC participants by 20 percentage points. Current rates are also below the Healthy People 2010 goals, which are to increase to 75 percent the women who breastfeed their babies in the early postpartum period, and increase to 50 percent the proportion of women who breastfeed their babies through 5 and 6 months of age.

Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages Study Overview

FNS has designed a study to collect and analyze data to evaluate the impacts that the regulatory changes to WIC food packages have on the incidence, duration, and intensity of breastfeeding. The overarching objective is to assess the effects of the WIC food package Interim Rule to be implemented by local WIC agencies (LWAs) for the first month and subsequent months postpartum.

The central features of the FNS design are:

- A base contract and funded optional task involving collection and analysis of
 - administrative data in 16 selected local WIC agencies (LWAs) both before and after the food package changes are implemented;
 - data on pre- and post-implementation site characteristics; and
- An option that includes interviews with WIC mothers as well as interviews with State and local WIC agency staff to gather information on local agency characteristics, the implementation process, and perceived impacts on mothers' infant feeding behaviors.

Study Objectives

The study involves the collection of data on the implementation of the Interim Rule in State and local WIC agencies as well as interviews with WIC recipients to obtain their perspective regarding their breastfeeding behavior and related factors, food package selections, and information they received from their local WIC agency. The information will provide a comprehensive and systematic description of the implementation process of the Interim Rule and will improve USDA's understanding of what effect, if any, it is making on breastfeeding incidence, duration, and intensity.

The data collected will cover the following domains: food package choices, breastfeeding initiation, breastfeeding duration, breastfeeding intensity, local WIC agency implementation, and WIC participation.

A.2 How the Information Will Be Used, By Whom, and For What Purpose

This section of the supporting statement provides an overview of the research design and data collection efforts planned to meet the overall objectives of the *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages Study*. The section begins with an overview of the research design, followed by a description of the data collection activities for which OMB clearance is requested. The final section describes how the information collected will be used.

Overview of the Research Design

This study relies on four main methods of data collection:

1. Interviews with staff from State WIC agencies;
2. Interviews with staff from local WIC agencies (LWA);
3. Interviews with WIC recipients; and
4. Administrative data collection from existing local WIC agency electronic data systems

Protocols are summarized below. Recruitment letters and data collection instruments are provided in this package. The sampling design that describes the process for selecting the subset of 16 LWAs is described in Section B.1.

Telephone and In-Person Interviews with State and Local WIC Agency Staff

Contracted project staff from Abt Associates will conduct telephone interviews with staff from the State WIC agency in those States where a local WIC agency is part of the sample. Telephone interviews will take place approximately three months before the State has implemented the Interim Rule. The purpose of the pre-implementation phone interviews is to provide information on the site characteristics and any efforts that have occurred to prepare local agencies for implementing the Interim Rule before it goes into effect. The post-implementation in-person interviews will take place with the same individuals who participated in the pre-implementation interviews with the purpose of describing the process of implementing the regulatory change, the State and local roles, and how and why the planned implementation varied from the actual implementation. Information will be gathered about training and information dissemination to WIC staff as well as planned and actual information dissemination to WIC participants. These interviews will occur approximately three months after a State has implemented the Interim Rule. Pre-implementation telephone and post-implementation in-person interviews will be conducted at the State level with the State WIC director, the breastfeeding promotion coordinator, and the State MIS administrator; and at the local level with the local WIC agency director, nutritionists, breastfeeding coordinator, and staff responsible for maintaining administrative data.

All telephone and in-person interviews will be conducted by trained data collectors. Telephone interviews will be conducted individually and last less than one hour each. The in-person interviews will take approximately 90 minutes to administer, but will be scheduled consecutively to allow for a

site visit that is no more than two days per LWA. Data collectors will prepare a brief report that summarizes all of the interviews associated with a particular LWA.

Prior to contacting any sites for the study, FNS will contact the FNS Regions to let them know which LWAs have been selected for the sample and to inform them that the contractor, Abt Associates, will be contacting LWAs and their respective State WIC agencies. After the FNS Regions have been informed, Abt will work with the FNS Regional Offices to contact the relevant States to inform them of the study.

After the States have been informed, Abt will send a letter of introduction to the LWA, signed by an FNS official. The letter will provide an overview of the study, a detailed description of the local WIC agencies' responsibilities in this study, and a request for their participation. A copy of the introduction letter will be sent to the State WIC agency with a list of LWAs selected in their State. Within one week of sending the letter, an Abt staff person will contact the director of the LWA to answer any questions and secure their cooperation. After we have received the LWA director's verbal agreement, we will ask for the names and contact information of key agency staff, followed by a confirming email to the LWA, copied to the State WIC director and the FNS regional official, thanking them for their cooperation and alerting them of the next steps in the process. If a site is not eligible or refuses to participate, the same process will be used for replacement sites.

WIC Participant Interviews

Obtaining the perspective of WIC participants will help us understand the impact of the Interim Rule on food package selection, breastfeeding behaviors, and a host of related topics. In particular, we are focusing on women who have infants age 60 days or younger, who initiated breastfeeding.² The sample of 1600 women (approximately 100 from each site) will be drawn from the 16 local agencies that are selected to participate in this evaluation study. A pre-implementation sample as well as a post-implementation sample of women will be recruited at each of the participating LWAs.

The interview instrument contains seven major sections and takes less than 30 minutes to complete. Each section title and purpose is described below.

- ***Infant Information and Feeding Practices:*** This portion of the interview acts as a screener for it confirms a WIC recipient's infant is of qualifying age (60 days or younger) and confirms that she attempted to breastfeed her infant at least once. The remainder of this section asks questions about infant feeding behavior during the last 24 hours.
- ***WIC Program Participation:*** This section asks when WIC certification was received, the kinds of breastfeeding information that was received, breastfeeding support at the hospital and other supports received outside of WIC.
- ***Food Package Choices:*** The purpose of this section is to learn if WIC recipients know the difference in food packages options available to them and their infants and if so, how they learned about the differences. This section also asks women if the amount of formula they receive matches their needs.
- ***Breastfeeding History, Knowledge About, Attitudes Towards, Decisions:*** This section establishes a woman's knowledge of infant feeding practices; influences that affected her

² At the time of certification, postpartum women are asked if they have ever breastfed their infants. The sample will be selected from among those women who have indicated that they have done so.

decision about what to feed her infant; her cultural approach to breastfeeding; and her breastfeeding history.

- **Employment:** The purpose of this section is to find out if a woman's employment has any impact on her ability/decision to breastfeed her infant.
- **Child Care:** This section asks if a woman is away from her infant for reasons other than work for a specified block of time.
- **Demographic Characteristics:** This section gathers information on a WIC recipient's household size and composition, marital/cohabitation status, education level, race and ethnicity, country of birth, date of birth, total household income, and receipt of other means-tested programs.

Abstraction from Existing WIC Program Data

Monthly administrative data on food package choices will be required from the 16 participating LWAs for the three months preceding and the nine months following implementation of the food package changes. We will need these data on linked dyads of mothers and infants through 5 months of age.³ In addition, in order to construct the WIC participant interview sample, we will ask that the monthly extracts include pregnant WIC participants and their expected delivery dates.

From the administrative data, we will be analyzing the food package choices and breastfeeding initiation rates of mother-infant dyads for **all** dyads with infants 0 through 5 months in the sample for the three months in the implementation period and for at least six months post-implementation. (We will track but may not use the data from the first three-month post-implementation in case there are aspects of the food package application process that are temporarily in flux.)

Among the sampled local offices and their corresponding States, we are likely to find that the agencies and offices vary in their capability to make these links. Our preferred scenario is that the State agency provides, for each sampled LWA, an electronic file each month that lists new and recertified WIC mother-infant dyads, with a unique identifier to match the records, along with demographic information. The monthly files will then be used to construct a longitudinal data set in which the mother-infant dyad records are linked for each month.

Exhibit A-1 shows the research questions, the outcome measures, and the source of the information.

³ Note that analyses of administrative data will be based on this broader set of participants, although the survey sample will include only mothers and infants up to 2 months of age.

Exhibit A-1

Research Questions, Outcome Measures, and Analysis Methods

Domain	Research Questions	Outcome Measures	Analysis Methods
Food Package Choices	1. What is the average percent of postpartum women selecting each food package pre-implementation and post-implementation by postpartum month? On average, how soon after giving birth do women receive their first non-pregnancy food packages? Are the pre- and post-implementation averages different and do they vary by month postpartum?	Food package chosen in each month	Tabulation, regression-adjusted tabulation
	2. Prior to the implementation of food package change, how do the choices of food packages for postpartum WIC participants change over the time they participate? What percent of them continue with the same package from one month to the next? How common is each pattern of change? Subsequent to the food package change, what are the patterns of continuation and change?	Series of food packages chosen over time	Tabulation
	3. What is the relationship between site characteristics and food package choices? Are the pre- and post-implementation relationships different?	Food packages chosen	Tabulation, regression
	4. What is the relationship between the demographic and program participation characteristics of postpartum women and their food package choices? Are the pre- and post-implementation relationships different?	Food packages chosen	Tabulation, regression
	5. Among breastfeeding initiators, what is the relationship between demographic, program participation, knowledge of infant feeding practices, and breastfeeding history characteristics and food package choice? Are the pre- and post-implementation relationships different?	Food packages chosen	Tabulation, regression
	6. Among breastfeeding initiators, how and why did women make their breastfeeding and food package choices?	Reported reasons for infant feeding and food package choices	Tabulation
	7. (a) For women who chose a fully breastfed package but who are actually partially breastfeeding: Why do these women choose the fully breastfed package? What is their knowledge of the food content of the fully formula fed package relative to the fully breastfed package? Where do these women obtain formula? What are the patterns of change among food package choices for women whose package choices differ from behavior? (b) For women who chose a fully formula fed package but who are actually partially or fully breastfeeding: Why do these women choose the fully formula fed package? What is their knowledge of the food content of the fully breastfed package relative to the fully formula fed package? What do these women do with any unused formula? What are the patterns of change among food package choices for women whose package choices differ from behavior?	Whether choice of package is consistent or inconsistent with behavior.	Tabulation, regression, qualitative analysis
	8. Among breastfeeding initiators, what do women perceive to be the impact of the food package choices on their breastfeeding behavior?	Perceived relationship between infant feeding and food packages chosen	Tabulation
	9. What is the mean initiation rate of breastfeeding among women overall, by food package choice, and pre- vs. post-implementation? Are the pre- and post-implementation rates different?	Breastfeeding incidence	Tabulation, regression-adjusted tabulation

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Exhibit A-1

A-10

Research Questions, Outcome Measures, and Analysis Methods

Domain	Research Questions	Outcome Measures	Analysis Methods	
Part A: Justification	ing Initiation	10. What is the relationship between the demographic and program participation characteristics of postpartum women and the initiation of breastfeeding? Are the pre- and post-implementation relationships different?	Breastfeeding incidence	Tabulation, regression
		11. What is the relationship between site characteristics and the initiation of breastfeeding? Are the pre- and post-implementation relationships different?	Breastfeeding incidence	Tabulation, regression
	Breastfeeding Duration	12. What is the duration of breastfeeding among women up to two months postpartum, overall, by food package choice, and pre- vs. post-implementation? Are the pre- and post-implementation distributions different?	Breastfeeding duration	Tabulation, regression-adjusted tabulation, life table analysis
13. What is the relationship between demographic, program participation, knowledge of breastfeeding practices, and breastfeeding history characteristics of postpartum women and duration of breastfeeding? Are the pre- and post-implementation characteristics different?		Breastfeeding duration	Tabulation, life table analysis	
14. What are the relationships between site characteristics and the duration of breastfeeding? Are the pre- and post-implementation relationships different?		Breastfeeding duration	Tabulation, regression, life table analysis	
Breastfeeding Intensity	15. What is the intensity of breastfeeding among women up to two months postpartum, overall, by food package choice, and pre- vs. post-implementation? Are the pre- and post-implementation distributions different?	Breastfeeding intensity	Tabulation, regression-adjusted tabulation	
	16. What is the relationship between the demographic, program participation, knowledge of breastfeeding practices, and breastfeeding history characteristics of postpartum women and intensity of breastfeeding (i.e., level or quartile)? Are the pre- and post-implementation characteristics different?	Breastfeeding intensity	Tabulation, regression	
	17. What are the relationships between site characteristics and the intensity of breastfeeding? Are the pre- and post-implementation relationships different?	Breastfeeding intensity	Tabulation, regression	
LWA Implementation	18. What role did the State play in coordinating the implementation of the food package changes? What kind of training was planned for local WIC directors and other staff? What did the WIC directors and staff receive? What written materials were provided by the State for use by local WIC directors, other local WIC staff, or participants? How were these materials used?	Implementation process conducted by State	Tabulation of staff responses, case studies	
	19. How was information on the new food packages disseminated to local WIC staff? How was staff informed of the change? What written materials did they receive? What kind of training did caseworkers receive? Who conducted it? What questions or concerns did local WIC staff have? How were these questions answered?	Information dissemination process to local WIC staff	Tabulation and qualitative analysis of staff responses	

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Exhibit A-1

Research Questions, Outcome Measures, and Analysis Methods

Domain	Research Questions	Outcome Measures	Analysis Methods
	20. How was information on the new food packages disseminated to WIC clients? How was the change publicized within the WIC clinic (posters, pamphlets, etc.)? Outside the WIC clinic? What written materials were made available to clients? Who prepared them? How did caseworkers explain the changes? At what point did the explanation occur (e.g., at certification, at nutrition education sessions)? How did planned dissemination of information to WIC participants vary from how information about changes in packages was actually communicated? What were the reasons for this difference?	Information dissemination process to WIC clients	Tabulation and qualitative analysis of staff responses
	21. In local communities, where else in addition to LWA offices was information about the changes in food packages disseminated (e.g., local hospitals, pediatric clinics) and how? How did planned dissemination of information vary from actual dissemination? What accounted for these differences?	Information dissemination process to community	Tabulation and qualitative analysis of staff responses
	22. What changes to systems and procedures were made to implement the food package changes? How long did it take for changes to be implemented fully? Did the transition period have an effect on the process of making food package choices (e.g., time periods for processing changes in food packages lengthened)?	Implementation process of LWA systems and procedures	Tabulation and qualitative analysis of staff responses
	23. What other activities exist in WIC agencies to promote breastfeeding, including Loving Support Peer Counseling? How were changes in packages coordinated with these efforts? Did the changes in WIC packages coincide with any changes/ adjustments in the delivery of other efforts to promote breastfeeding?	(Changes in) other breastfeeding promotion in LWA	Tabulation and qualitative analysis of staff responses
	24. Did local WIC agencies track the effects of food package changes on breastfeeding outcomes? What data were collected related to breastfeeding outcomes? How were these data collected and used?	Implementation data collection	Tabulation and qualitative analysis of staff responses
	25. What was the reaction of WIC staff to the changes in packages? What were the concerns/ considerations voiced by WIC participants when determining which package to choose? Did these concerns and considerations change over the period of implementation? If so, why?	Reaction of WIC staff, concerns and consideration of WIC participants	Tabulation and qualitative analysis of staff responses
	26. What do WIC staff think the reasons are that women change from the fully breastfed package to another food package? To what degree do they think that the changes in food package options have influenced this choice? If they believe that the change from the fully breastfed package was due to difficulties with breastfeeding, what supports were offered to help the women with breastfeeding (e.g., referral to local Loving Support peer counseling)? Did staff believe that these efforts had an effect on WIC participants' continuation of breastfeeding?	LWA staff perceptions of package choice	Tabulation and qualitative analysis of staff responses
	27. How did WIC staff perceive that the rule affected breastfeeding outcomes (initiation, duration and intensity) among WIC participants? What evidence did they have, including anecdotal information?	LWA staff perceptions of breastfeeding outcomes	Tabulation and qualitative analysis of staff responses
WIC Participa- tion	28. What is the mean WIC reenrollment rate among women who participated during pregnancy, pre- vs. post-implementation, for postpartum months 0 through 5? Are the pre- and post-implementation rates different?	WIC reenrollment rate	Tabulation, regression-adjusted tabulation
	29. What is the mean WIC enrollment rate among women who did not participate during pregnancy, pre- vs. post-implementation, for postpartum months 0 through 5? Are the pre- and post-implementation rates different?	WIC reenrollment rate	Tabulation, regression-adjusted tabulation

Use of the Information

Results of this study will provide the first examination of the effects of the changes in packages for postpartum women and infants on the initiation, intensity, and duration of breastfeeding. The interviews with State and local WIC agency staff will allow FNS to identify lessons learned and successful approaches used by State agencies with respect to the implementation process. The interviews with WIC recipients will provide information about whether women who are undecided about breastfeeding make choices based on the more economically attractive food package option and other influences in her decision of what to feed her infant. There is currently no other national effort that can address the research objectives of the proposed study. Without the proposed study, FNS would not obtain an understanding of the effects of the Interim Rule. There would be no information base upon which to direct future food package options that promote breastfeeding.

A.3 Use of Improved Information Technology to Reduce Burden

The study strives to comply with the E-Government Act of 2002 (Public Law 107-347, 44 U.S.C. Ch 36) by using various methods to facilitate convenient, timely, and accurate collection of information. To expedite and standardize data collection, the interviewer will administer the WIC participant interview instrument using a computer-assisted personal interviewing (CAPI) system. The CAPI administration of the instrument has several major benefits: (1) reducing the respondent burden by automating interviewer instructions and skip logic so that the interviews progress quickly and smoothly from question to question; (2) minimizing interviewer error through control over questionnaire logic, consistency checks, and probes; (3) eliminating the need to call back respondents to obtain missing data since errors and inconsistencies are corrected during the interview process; and (4) reducing the data editing tasks post-collection, through the use of soft and hard edits and consistency checks. If the interview is done by telephone, sensitive questions can be answered using a device known as the Digit Grabber® to increase item response rates. During telephone data collection, the Digit Grabber® allows respondents to select an answer using the telephone keypad instead of communicating their choice verbally. The system then displays this selection on the interviewer's computer screen and automatically uploads the data to the CAPI system.

The use of CAPI will eliminate two common sources of poor quality data: missing and inconsistent data. The CAPI system is programmed to prevent data entry errors and ensure data quality, but the system is not overly complicated, nor does the system increase respondent burden. Valid value ranges are programmed for each question. If an attempt is made to enter an out-of-range value, a warning message is displayed on the screen and the CAPI system will not proceed to the following question until the invalid value has been corrected. The CAPI system also performs inter-item consistency checks, alerting interviewers of data that should be checked and confirmed with respondents at the time of the interview. The checks the CAPI system performs increase the accuracy of the data being collected and reduce resources needed for data cleaning.

Sample tracking will be managed by our Field Management System (FMS), a major application composed of a set of interrelated applications that control all aspects of sampling, data collection, data cleaning, and delivery of survey data.

The WIC participant interview is comprised of short, close-ended questions. The exception is for questions that have an "Other" category that may be selected, in which case respondents must specify their response that is then filled in by the interviewer. On average, the survey will take respondents

less than 30 minutes to complete. Variation in timing is due to several factors, including respondents skipping out of questions that are not relevant to their situation, respondents taking more time to answer items, and some respondents needing more clarification and probing than others, which can extend the time to complete. We will be obtaining data abstractions from existing data on food package choices and analyzing them to eliminate the need to ask WIC participants these questions.

Open-ended telephone and in-person interviews will be used for interviews with State and local WIC agency staff. This is required due to the varied contexts and implementation strategies of the Interim Rule. As a result, these will not be administered using a CAPI system but will be administered manually. Telephone interviews conducted with State and local WIC agency staff will last less than one hour. In-person interviews will last approximately 90 minutes. In addition, any information that we can obtain by abstracting data from existing local WIC agency data files such as food package choices will not be asked during interviews with State and local agency officials to reduce unnecessary burden.

A.4 Efforts to Identify and Avoid Duplication

There are no similar data collection efforts available.

A.5 Efforts to Minimize Burden on Small Businesses or Other Entities

No small businesses or other entities will be involved in the proposed data collection effort.

A.6 Consequences of Less Frequent Data Collection

This is a single time study. The data collection for the proposed study will be conducted at two points in time: before local WIC agencies implement the Interim Rule, and soon after they implement the Interim Rule. Two data collection periods are needed to understand if the Interim Rule has any impact on women's food package selections as well as their infant feeding behavior. It is important to note that we will not interview the same WIC participants at two points in time but rather, there will be a cohort of women interviewed before the Interim Rule is implemented that is compared to a similar cohort of women that is interviewed after the Interim Rule is implemented. In order to understand and interpret the findings from the WIC participant interviews and analysis of WIC food package data, it will be important to understand key contextual information about the sites, the plans for implementation, and whether the implementation was executed as planned. Data collection from State and local officials at two points in time are necessary to reduce the risk of recall bias about pre-implementation conditions if interviews were only conducted six months after the implementation of the Interim Rule occurred.

A.7 Special Circumstances Related to the Guidelines of 1320.5

There are no special circumstances.

A.8 Federal Register Notice and Efforts to Consult with Persons Outside the Agency

A notice was published in the *Federal Register* on June 18, 2008 (73 FR 34702).

FNS received one response to the Federal Register Notice (included in Appendix B). The respondent commented that it believed that the study to measure and evaluate the impact of the breastfeeding package changes is necessary. It recommended that the study include data on several issues, each of which are addressed separately.

1) *“The evaluation...should focus on tracking postpartum women who choose partial breastfeeding and determine whether the women continue partial breastfeeding, or if they switch to fully formula feeding or fully breastfeeding after the first month postpartum. The tracking must occur on a monthly basis for the child’s first year of life.”*

Response: We will be tracking food package choices of WIC participants for the first six months postpartum, both prior to and after the Interim Rule is implemented. We chose this time period because, at six months, research indicates that currently 78% of WIC participants had discontinued breastfeeding.⁴ Given the need to make findings available as soon as possible, we believe that tracking food package changes for six months postpartum will be sufficient; over that time period the study is likely to capture use of the partial and full breastfeeding packages for the vast majority of WIC participants.

As reflected by the supporting material, we will be interviewing WIC participants about their breastfeeding behaviors during their first 60 days postpartum, as opposed to spreading the sample over six months (or one year). We decided to limit the sample to the first 60 days postpartum because the study has limited resources. Data from WIC Participant Characteristics (2006) indicate that, among infants who were ever breastfed, 22% were weaned in a week or less; 50% were weaned in 6 weeks or less; and 65% were weaned in 13 weeks or less. We believe that therefore we are likely to detect the greatest impacts of the first-month food package changes on both the intensity and duration of breastfeeding within the first 60 days postpartum and have maximized our ability to detect these effects by limiting the sample to this time period.

2) *“Further, the study should document current baseline feeding practices and correlate them to patterns of weight gain, hyperbilirubinemia, hospitalization due to dehydration, and failure to thrive, and compare the data to the occurrences after the new policy is implemented.”*

Response: The purpose of the study is to determine the effects of the changes in the WIC breastfeeding food packages on breastfeeding behaviors. Therefore, we will be interviewing WIC participants about their feeding practices prior to when the Interim Rule is implemented as well as after it is implemented. It is beyond the scope of the study, however, to determine the effects of these changes on infants’ health status.

3) *“Given the known ethnic and racial difference in breastfeeding initiation and continuation rates, the study must also measure any differential effects of food package changes to ensure children and mothers of all races and ethnicities have equal access to the best nutritional practices possible.”*

⁴ Abbott Laboratories, 2003.

Response: We have stratified our site selection to ensure that the sample includes LWAs that serve WIC participants who are predominantly (at least 60 percent) non-Hispanic black, predominantly non-Hispanic white, predominantly white, and all other. We will gather data about local agency efforts to support WIC participants’ breastfeeding practices. It also may be possible to detect differences in outcomes among WIC participants with different racial and ethnic backgrounds; however, due to the sample size of 1600 participants, these differences will need to be large in order to be detected.

4) *“In addition, the Interim Rule evaluation should address the impact of food package changes on women who may wish to fully breastfeed but unable to do so. The study should examine the reasons why mothers discontinue fully breastfeeding, including returning to work or school, or whether these women have adequate access to breast pumps and support services that may be necessary to comply with the food package changes.”*

Response: These issues are addressed by the study.

5) *“The evaluation should also obtain data on prenatal care and the prevalence of prenatal breastfeeding education to measure the influences of such initiatives.”*

Response. We will collect information from WIC participants about the information that they received related to breastfeeding and the source(s) of that information including staff from WIC, doctors’ offices, health clinics, hospitals, etc. However, it is beyond the scope of the study to measure the prevalence of breastfeeding education.

6) *“Finally, a review of WIC clinic staff training should be conducted.”*

Response. We will collect detailed information about training of WIC staff as it relates to the breastfeeding food package changes. As part of the contextual information gathered through state and local interviews, we will also collect general information about WIC clinic staff training related to breastfeeding. However, this study does not do a thorough review of staff training to support WIC participant breastfeeding, as it is beyond the scope of this study. FNS currently has another related study in the field, the WIC Peer Counseling study. For that effort, FNS is conducting a full review of training to support breastfeeding to WIC peer counselors and related staff.

Consultations Outside the Agency

In addition to the public comments above, consultations with experts in technical and substantive areas occurred throughout the design, instrument development, and data collection planning, and will continue to take place throughout the study. These individuals are:

Joan McLaughlin, Ph.D., Abt Associates, Inc.

Fred Glantz, Ph.D., Kokopelli Associates LLC

Nancy Burstein, Ph.D., Consultant

Janet Allen, MA, RD, LD, North Central Florida Maternal and Infant Care Project

Linda Kilby, Executive Director/WIC Program Director, NORTH Inc., Philadelphia, PA

Rhonda Buntrock, North Dakota State Department of Health

A.9 Payments to Respondents

Data collection for the WIC participant interview portion of this study includes a \$35 payment to respondents in the form of a flexible gift card that is useable at numerous retail establishments. Because of the burden this interview may cause for this population, we propose offering this small monetary payment to respondents. We understand that finding up to a half-hour to participate in an interview when there is a new baby in the family is a burden to mothers for which compensation can be justified. Additionally, respondents will be asked to recall the details for information they received and to report on sensitive information such as what they do with extra formula they receive. We anticipate that offering this payment will increase the rate of response and therefore reduce overall cost as nonresponse follow-up activities should be reduced. We believe this reimbursement for time and services is large enough to obtain the desired response rate, yet not so large that it will coerce women into responding. Women who are interviewed over the phone will be mailed gift cards after completion of the interview, while women who are interviewed in-person will receive payment on the spot.

A.10 Assurance of Confidentiality

The Privacy Act of 1974 requires that before personal identifying information may be shared with other entities, a Privacy Act notice must first be published. Therefore, the Food and Nutrition Service published such a Privacy Act notice (system of records) titled *FNS Studies and Reports, FNS – 8* to specify the uses to be made of the information in this collection. The individuals participating in this study will be notified that the information they provide will not be released in a form that identifies them except as required by law. No identifying information will be attached to any reports or data supplied to USDA or any other researchers.

Abt Associates Inc. has extensive experience in data collection efforts requiring strict procedures for maintaining the confidentiality, security, and integrity of data. The following data handling and reporting procedures will be employed to maintain the privacy of interview participants and composite electronic files.

- All project staff, both permanent and temporary, will be required to sign a confidentiality and non-disclosure agreement. In this agreement, staff pledges to maintain the confidentiality of all information collected from the respondents and will not disclose it to anyone other than authorized representatives of the evaluation. Field data collectors are required to carry their signed pledge with them at all times while in the field and may be required to show it to respondents. Issues of confidentiality are also discussed during training sessions provided to staff working in the project.
- Recruitment for the WIC participant interviews will require short-term maintenance of lists that include name, address, and telephone number of WIC recipients with infants up to 60 days old. This information is necessary to sample, locate, and confirm women's participation in WIC and set up an interview time. Only project staff who signed pledges of confidentiality will have access to these lists, which will be stored either in locked storage files or in password protected electronic data files. As interviews are completed, identifying information will be separated from completed interview data. All lists and

data files that contain personal identifiers will be destroyed at the conclusion of the project.

- While in the field, data collectors are required to store all completed forms, interviews and other materials with identifying information in a locked car trunk. If the data collector is in the field for several days, forms and materials are shipped to the central (Cambridge, Massachusetts) office by Federal Express, UPS or other traceable shipping service. Regular mail is not used to ship any material containing respondent information. Field staff is also instructed to avoid making photocopies of such material.
- Once in the central office, documents containing respondent information are kept in locked files cabinets. At the close of the study, such documents are shredded.
- Data gathered from the participant interviews will be transmitted into a secure datafile, containing a unique identification number but stripped of all identifying information.
- Data from State and local WIC officials' interviews will be aggregated without any respondent-identifying information and will be contained and protected in secure storage, to which only a limited number of project staff pledged to maintain confidentiality will have access.

In addition, the evaluation contractor has established a number of procedures to provide the confidentiality and security of electronic data in their offices during data collection and processing period. Standard backup procedures will be implemented for the central office computer system to protect project data from user error or disk or other system failure. Backups and inactive files will be maintained on tape or compact disks. The system servers will be maintained inside a secure locked area accessible only to authorized systems personnel. Files will be accessible only by authorized personnel who have been provided project logons and passwords. Access to any of the study files (active, backup, or inactive) on any network multi-user system will be under the central control of the database manager. The database manager will ensure that the appropriate network partitions used in the study are appropriately protected (by password access, decryption, or protected or hidden directory partitioning) from access by unauthorized users. All organizations using data on study participants will maintain security, virus, and firewall technology to monitor for any unauthorized access attempts and any other security breaches.

A.11 Justification for Sensitive Questions

The data collection instruments for the State and local WIC agency staff portion of the study do not contain questions of a sensitive nature. However, the instrument for the WIC participant interview is designed to describe infant feeding practices, participation history with the WIC program and information received, and food package choices to be able to assess what influences women's decisions. A few items refer to a woman's personal circumstances and behaviors that may be sensitive for some respondents. For example, to assess if women are selecting food packages that meet their infant feeding needs, it is necessary to ask what she feeds her baby if she does not have enough formula. Similarly, for women who indicate they receive more formula than they need from WIC, it is necessary to ask what she does with the extra formula. Other aspects about women's circumstances that may be considered sensitive include questions about employment, education level, race and ethnicity, marital status, and household income. These demographic variables are important for conducting the data analysis.

Interviewer training for the study will stress the importance of asking all questions that involve sensitive issues in a professional and non-judgmental manner. In addition, for in-person interviews, field staff will offer to turn the keyboard towards the respondent and provide simple instructions necessary for a respondent to make her own selection while protecting her privacy. If the interview is done by telephone, sensitive questions can be answered using a device known as the Digit Grabber® to increase item response rates. During telephone data collection, the Digit Grabber® allows respondents to select an answer using the telephone keypad instead of communicating their choice verbally. The system then displays this selection on the interviewer's computer screen, and automatically uploads the data to the CAPI system. Finally, women will be notified that participation in the study is voluntary and there will be no penalties if they decide not to respond to either the information collection as a whole or to any particular questions.

A.12 Estimates of Respondent Burden

Exhibit A-2 presents our estimates of the annual reporting and cost to respondents for the study instruments described in Section A.2. Time estimates are based on experience with similar instruments in similar studies. The estimated cost to respondents has been calculated using average hourly rates for respondents obtained from FNS' 2006 WIC Staffing Data Collection Project⁵, which provides detailed wage information for WIC staff, and from the Bureau of Labor Statistics' estimates for occupational wages (www.bls.gov/bls/wages.htm).

A.13 Estimates of Other Annual Costs to Respondents

There are no capital and startup costs or operation and maintenance costs associated with this data collection for respondents.

A.14 Estimates of Annualized Government Costs

The period of performance for this task order is from September 30, 2007 through May 31, 2011. The data collection component will occur between February 2009 and February 2010. The cost to the Federal government for the design, recruitment of local WIC agencies, data collection, analysis of data, report writing, and federal government review and oversight is \$2,437,840.

⁵ WIC Staffing Data Collection Project," Special Nutrition Program Report Series, No. WIC-05-WS, Project Officer: Ed Herzog. U.S. Department of Agriculture, Food and Nutrition Services, Office of Analysis, Nutrition, and Evaluation, Alexandria, VA: 2006.

Exhibit A-2. Estimate of Response Burden

Respondent by Instrument	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Burden Hours per Response	Total Burden Hours	Estimated Cost to Respondents
<i>State WIC Agency Pre-Implementation Interview</i>						
State WIC director	16	1	16	1	16	\$502
State breastfeeding coordinator	16	1	16	1	16	\$423
State lead nutritionist	16	1	16	1	16	\$367
State WIC MIS administrator	16	1	16	1	16	\$876
<i>State WIC Agency Post-Implementation Interview</i>						
State WIC director	16	1	16	1	16	\$502
State breastfeeding coordinator	16	1	16	1	16	\$423
State lead nutritionist	16	1	16	1	16	\$367
State WIC MIS administrator	16	1	16	1	16	\$876
<i>Local WIC Agency Pre-implementation Interview</i>						
Local WIC agency director	16	1	16	1	16	\$450
Local WIC breastfeeding coordinator	16	1	16	1	16	\$318
Local WIC nutrition specialist	16	1	16	1	16	\$385
Local WIC nutritionists	32	1	32	1	32	\$714
Local WIC agency database manager	16	1	16	1	16	\$226
<i>Local WIC Agency Post-implementation Interview</i>						
Local WIC agency director	16	1	16	1.5	24	\$675
Local WIC breastfeeding coordinator	16	1	16	1.5	24	\$477
Local WIC nutrition specialist	16	1	16	1.5	24	\$578
Local WIC nutritionists	32	1	32	1.5	48	\$1071
Local WIC agency database manager	16	1	16	1.5	24	\$339
<i>WIC Participant Pre-implementation Interview</i>						
WIC participants-- respondents	640	1	640	.5	320	\$0
WIC participants-- non-respondents	160	1	160	.05	8	\$0
<i>WIC Participant Post-implementation Interview</i>						
WIC participants-- respondents	640	1	640	.5	320	\$0
WIC participants-- non-respondents	160	1	160	.05	8	\$0
Total	1600		1600		1024	\$9,569

Abt Associates Inc.

Part A: Justification

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A.15 Changes in Hour Burden

This is a new collection of information. It will add 1,024 hours to the OMB collection inventory.

A.16 Time Schedule, Tabulation, Publication, and Analysis Plans

This section describes the schedule for the project, along with plans for analysis.

Time Schedule

The schedule shown in Exhibit A-3 lists the expected period of performance for data collection and reporting.

Exhibit A-3

Anticipated Schedule for Data Collection and Reporting

Activity	Time Schedule
OMB approval	December 2009
Collect data (State and local agency staff interviews; participant interviews, administrative data abstracts)	January 2009 – May 2010 ⁶
Create data files and conduct analysis	June 2010 - December 2010
Prepare final report	January 2011 – May 2011

Outcome Measures

The *Evaluation of the Birth Month Breastfeeding Changes to the WIC Food Packages* study will generate qualitative and quantitative data collected from multiple sources. The plans for the separate components to be analyzed are as follows:

Food Package Choices

Food package choices will be measured for all mothers and infants in each selected site using administrative data. We plan to analyze these choices in terms of broad packages, not the specific items and quantities prescribed for each individual participant, with the exception of infant formula. It is of great interest whether infants are prescribed the maximum allowable amount of formula or some lesser amount. A measure of prescribed amount will be constructed based on data on quantities and forms (ready-to-feed, powder, or concentrate).

Breastfeeding Initiation

Breastfeeding initiation will be measured using administrative data, as reported on infants' certification records. We wish to measure program impacts for all women who could be affected, because they participated in WIC while pregnant, because they participated in WIC postpartum, or both.

⁶ The actual schedule of data collection will be dictated by when States implement the new Interim Rules. The total data collection period in any site will be approximately 12 months. The total data collection period will last approximately 18 months.

Breastfeeding Duration

Breastfeeding duration will be measured by asking all WIC participants whether they are currently breastfeeding or, if not, when they stopped. Life table analysis will be used to determine duration patterns. The interviews will be conducted with women who are currently in Weeks 0 through 9 postpartum. To calculate mean and median duration of breastfeeding for this group of women, we assume that the cohorts that are interviewed in Weeks 0, 1, 2, etc. postpartum are following similar patterns of infant feeding.

Breastfeeding Intensity

The simplest measure of breastfeeding intensity is a dichotomous indicator of exclusivity: full vs. partial breastfeeding. We will collect data to create this measure and also use an additional approach to obtain more detail on intensity, which will be to ask a direct question with more finely divided categories, based on an item used by Abt Associates in a previous study on infant feeding behaviors.

Policy Implementation

We will measure aspects of the implementation of the Interim Rule through interviews with State and local WIC agency staff. The outcome measures for this question will come from the local agency interview questions asking how information on the new food packages was communicated to local WIC staff, whether the staff received written materials about the new food packages, what kind of training each staff in each position (WIC director, WIC nutrition staff, etc.) received, who conducted the training for staff in each position, etc. Answers to these questions will be summarized across the 16 different sites, describing variations in implementation approaches and the ways in which implementation was planned and varied from the plan, and the perceived consequences of those variations.

WIC Participation

The changes in the food package may affect women's decisions about whether and when to enroll in WIC. Using administrative data, we will measure the following outcomes:

- Of women ***participating in WIC in the last month of pregnancy***, how many
 - Participated in the birthmonth?
 - Did not participate in the birthmonth, but participated at some point in Months 1-5?
 - Did not participate in WIC anytime in the first 6 months postpartum?
- Of women not enrolled in WIC in the last month of pregnancy, but ***participating in Months 0-5 postpartum***, how many
 - Participated in the birthmonth?
 - Did not participate in the birthmonth, but participated in Months 1-5?

We will restrict our attention to women who participate in WIC ***at some point*** before or after the birth, rather than the broader population of women who are eligible for WIC. We assume that the food package change neither (a) draws women in who otherwise would not have participated in WIC at all, nor (b) drives women out who otherwise would have participated in the postpartum period exclusively.

Analysis Methods

The analysis of data from the interviews will be performed starting in the spring of 2010. The results will be presented in the study's final report and LWA-specific information will be given to each

participating LWA. The final report will synthesize all study results and offer information that is vitally important to understanding the implementation of the Interim Rule from an administrative perspective as well as WIC participants’ perspective. Here we describe the analytic methods we will apply to the outcome measures described above in order to answer the research questions.

Method 1: Tabulation

Tabulation will be used to address every research question, although some questions will require additional analysis. For each question we will develop tables, charts, and graphs to display the information. Many of these tabulations will be quite simple and direct. For instance, RQ20 asks how the information on the new food packages was disseminated to WIC clients. Most questions will involve this sort of simple direct tabulation. We expect that as the months progress many infants and mothers will be switching from the breastfeeding packages to the formula feeding package, and from the full breastfeeding package to the partial breastfeeding package.

The data for this question will come from the abstract of administrative data, which will be obtained by *calendar month*. It will be analyzed; however, by *months postpartum*, and by whether the infant’s birthmonth occurred before or after the implementation of the regulatory change. We will then use transition matrices to look at how food package choices change from Month 0 to Month 1 postpartum (Exhibit A-4). We note that there are four “states”: 1) receipt of the full breastfeeding package, 2) receipt of the partial breastfeeding package, 3) receipt of the full formula package, and 4) exiting WIC.

Exhibit A-4

Transition Matrix of Food Package Choices between Month 0 (Birthmonth) and Month 1 Postpartum^a

Food package choice in birthmonth (prior to regulatory change)	Food package choice in Month 1 postpartum				Total
	Full Breastfeeding	Partial Breastfeeding	Full Formula Feeding	WIC Exit	
Full Breastfeeding Package	X_{11}	X_{12}	X_{13}	X_{14}	100%
Partial Breastfeeding Package	X_{21}	X_{22}	X_{23}	X_{24}	100%
Full Formula Feeding Package	X_{31}	X_{32}	X_{33}	X_{34}	100%

a These three choices represent three possible combinations of mother and infant packages. The full breastfeeding choice is the fully breastfeeding package for the mothers and none for the infant. Partially breastfeeding is the partially breastfeeding package for the mother and a partial formula prescription for the infant. Fully formula fed is the full formula feeding package for the mother and the full formula allotment for the infant.

In the first row of Exhibit A-4, among these dyads who chose the full breastfeeding food package for the birthmonth (Month 0), X_{11} will indicate the proportion who chose the same package in Month 1 postpartum; X_{12} is the proportion who chose partial breastfeeding in Month 1; X_{13} is the proportion who chose the full formula feeding package; and X_{14} is the proportion who exited WIC. The numbers in each row sum to 100, because they show all the possible choices that could be made in Month 1 postpartum. The diagonal elements of this matrix (X_{11} , X_{22} , and X_{33}) show the percent of dyads in each row that continued with that same package in Month 1 postpartum; the off-diagonal entries show the patterns of change of those who change packages. The fourth column, X_{14} , X_{24} , and X_{34} , shows the percent of dyads in each row that no longer participated in WIC in Month 1.

As the food package choices are the same each month, we expect most participants will continue with the same package. This means that the numbers along the diagonal will be large. We also expect X_{12} and X_{23} to be relatively large because mothers switching from exclusive to partial breastfeeding, and from partial breastfeeding to exclusive formula feeding are both common occurrences in Month 1. We expect the other numbers to be smaller, however, especially the numbers below the diagonal. Behavioral switching from exclusive formula feeding to partial or exclusive breastfeeding, or from partial to exclusive breastfeeding, is unusual, so the corresponding food package changes will also be rare.⁷

We expect the entries in this matrix to change when we look at the dyads where birth occurred **after the food package change**. The change in birthmonth food packages will most likely cause changes in the transition among different packages.

Corresponding to the rows of the transition matrices, we will analyze and display rates of transition from month to month postpartum conditional on the “state” in the earlier month. For example, we will show, for women who received the full breastfeeding package in the first month postpartum, the proportion who were in each of the four states in the second month postpartum. Then, for women who received the full breastfeeding package in the second month postpartum, we will show the proportion who were in each of the four states in the third month postpartum; and so on. Because the four states sum to 100 percent, the results can be displayed as stacked bars.

Method 2: Regression-Adjusted Tabulation

Several research questions (numbers 1, 9, 12, 15, 28, 29) ask about how a particular mean or proportion—percent selecting each food package, breastfeeding incidence, duration, and intensity, and WIC participation rate—is different pre-implementation and post-implementation. Factors other than the change in food packages may occur between the pre and post periods, including the demographic composition of the sampled participants.⁸ To control for the possible effects of such changes, we will analyze these questions using **regression-adjusted tabulation**. For these questions we will run regressions of the variables of interest on participant demographic and socioeconomic characteristics in the pre-implementation period, display the adjusted pre- versus post-implementation comparison in simple tables or charts, and conduct statistical tests of significance of differences.

For the vector of maternal characteristics, we will have data on a wide variety of demographic and socioeconomic factors. Maternal demographic characteristics that we expect may be related to breastfeeding intensity include:

- Race
- Ethnicity
- Age
- Income
- Education level
- Marital status
- Breastfeeding history for prior pregnancies
- Whether mother or siblings were breastfed

⁷ ⁶ But not impossible. A mother who initially chooses a full formula package may find she is succeeding at breastfeeding and change her package to reflect this.

⁸ Note that, even if the overall demographic composition of the WIC caseload does not change, sampling error will likely cause differences between the pre and post samples.

- WIC participation history for prior pregnancies
- State or country of birth (with necessary grouping to account for sample sizes)

The regression-adjusted comparison will be carried out by regressing the outcome on characteristics listed above for mothers of infants born in the “pre” period, applying the model to the “post” period sample demographic characteristics, and then using the predicted value as the regression-adjusted “pre” value, to be compared with the actual “post” value.

Method 3: Regression

Research questions 3, 4, 5, 7, 10, 11, 14, 16, 17 ask about how a given measure—of food package choices or breastfeeding initiation, duration, or intensity—is related to site characteristics or the characteristics of the women in the study. These questions will be analyzed using **regression** as well as tabulation. The regression models will be the same as those used to produce the regression adjustments to the tabulations that were described above, relating food package choices and breastfeeding outcomes to mothers’ race, ethnicity, age, income level, and other characteristics, separately for the pre- and post-implementation samples. For the questions referring to site characteristics, regression analysis will show the multivariate relationships of the various outcomes with staff-to-participant ratios, numbers of peer counselors, region of the country, and so on. In contrast to the regression-adjusted tabulations, the focus for these research questions is on the coefficients of the estimated models, not simply the predicted values.

Method 4: Life Table Analysis

Finally, for research questions 12, 13 and 14 pertaining to breastfeeding duration during the first 60 days postpartum, **life table analysis** will be used to create the measure of breastfeeding duration, as described in the outcomes measures section. For research question 13 we will then extend the analysis in order to characterize women in the various quartiles of breastfeeding duration. We will estimate a set of equations of the form:

$$\text{prob (breastfeed for } > j \text{ weeks | breastfeed for at least } j \text{ weeks)}_i = f (X_i),$$

where the probability on the left is the breastfeeding continuation hazard rate, and X_i is a vector of characteristics describing dyad i , e.g., mother’s race, ethnicity, age, marital status, and so on. These equations will allow us to assign week-to-week hazard rates to every woman in the sample, based on her characteristics (the X_i ’s). We can then infer the expected value of each woman’s breastfeeding duration. Although these imputations will have errors for the individual women, over predicting duration for some and under predicting for others, under the usual assumptions the expected values will be correct conditional on the women’s characteristics. Hence we will be able to describe the quartiles of duration in terms of these characteristics.

Method 5: Case Studies

Finally, the 16 sites will provide FNS with important case studies of the ways in which the change in the rule was planned versus executed, staff perceptions of effects, and how these may relate to underlying site characteristics. Therefore, in addition to other analyses, we will prepare case study descriptions of the 16 LWAs. These case studies, in addition to tabulations, will provide answers to questions 18 through 27.

As part of the analysis, these detailed case studies will describe how the State- and agency-level policies and procedures are actually implemented at the service delivery level. The case studies will

be largely descriptive, but will also allow for an assessment of whether the rules changes are implemented according to established policies or if there are variations between practices and documented policies and procedures. Thus, in addition to allowing for a richer descriptive structure in the study, the case studies will constitute a face validity test of the degree to which the State-level information matches activities at the service delivery level.

Publication of Study Results

The study's findings will be presented in a final report for the project. FNS will make the final report and executive summary available on its web site.

A.17 Display of Expiration Date for OMB Approval

All data collection instruments will display the OMB approval number and expiration date. For telephone interviews that are conducted in CAPI, the OMB number and expiration date will be available on the initial screen and will be read to participants as needed.

A.18 Exceptions to Certification Statement

There are no exceptions to the Certification for Paperwork Reduction Act (5 CFR 1320.9) for this study.

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